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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 10/630,059 | 07/30/2003 | Brian Eugene Baldwin | 50012-00027 | 7769 |
| 25231 | 7590 | 07/08/2004 | EXAMINER | |
| MARSH, FISCHMANN & BREYFOGLE LLP 3151 SOUTH VAUGHN WAY SUITE 411 AURORA, CO 80014 | | | NASH, BRIAN D | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 3721 | |

DATE MAILED: 07/08/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/630,059

Applicant(s)

BALDWIN ET AL.

Examiner

Brian D Nash

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 May 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 and 31-42 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-17 and 31-42 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 July 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 10/14/2003.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Examiner's Comments

1. This action is in response to applicant's amendment received 27 May 2004. Applicant has remedied the notation of amended claims 5 and 7 and added new claims 31-42; however no formal election of claims has been made. The pending claims are 1-17 and 31-42.
2. With the cancellation of claims 18-30, the examiner construes applicant's amendment as an election of Group I, claims 1-17, drawn to a process for filling syringe bodies with a specific amount of fluid via pressurized injection. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Specification

3. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. It is suggested that the title be changed to "METHOD FOR FILLING, HANDLING, AND CAPPING SYRINGES"

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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5. Claims 1-17 and 31-42 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 1 and 34, lines 7 and 8 respectively, the terminology “one of the caps” is vague, indefinite, and confusingly worded because it is not clear what applicant is claiming.

Specifically, it is not clear if there are one or multiple caps for each syringe.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1-4, 9, 11-13, 16-17, and 34-37 are rejected under 35 U.S.C. 102(b) as being anticipated by US 5,884,457 to Ortiz et al. Ortiz et al show the same invention including a method for filling a plurality of syringe bodies wherein the syringe body is held, a cap is removed from a dispensing end, the syringe is filled from the dispensing end (66), and a cap is replaced onto the dispensing end (see Fig. 7G). Ortiz et al further show removing the cap via automated movement between a cap removing suction (54) and the syringe-dispensing end (again see Fig. 7G).

It is noted that Ortiz et al do not show a specific step of placing a cap onto the syringe bodies; however, the sterilized syringe bodies of Ortiz et al begin with a cap and it is therefore inherent that the step of placing a cap onto the syringe bodies occurs prior to the holding step.

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Furthermore, Ortiz et al disclose the syringe bodies to be sterile at the beginning of the filling process and that operations are performed in a sterile environment (see column 14, lines 19-25).

It is therefore also inherent that syringe bodies are sterilized prior to the holding step.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,884,457 to Ortiz et al. As stated above in this office action, Ortiz et al disclose the invention substantially as claimed, but do not show sensing the position of a plunger end thereof to terminate the filling step. However, Ortiz et al disclose an automated process in which a programmable pump delivers a predetermined and accurate amount of fluid is pumped into the syringe body. It would have been an obvious matter of design choice to use a sensor on the syringe body to determine when to terminate filling since the applicant has not disclosed that using a sensor in place of a programmable pump solves any stated problem or is for any particular purpose and it appears that the invention would perform equally well with either design choice.

Allowable Subject Matter

10. Claims 5-8, 10, 14, 31-33, and 38-42 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

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Conclusion

11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Vacca, Smith et al, Reinhard et al, Porfano et al, Reilly et al, and Odell et al are cited to show related references.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Nash whose telephone number is (703) 305-4959. The examiner can normally be reached on Monday – Thursday from 8 a.m. to 5 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Rinaldi I. Rada can be reached at 703 308-2187.

The fax number for this Group is: 703-872-9306

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1148.

Brian D. Nash
6 July 2004



SCOTT A. SMITH
PRIMARY EXAMINER